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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,351	10/31/2003	Ronald James Jandacek	9129L	2523

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1614

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DELIVERY MODE

02/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,351

Applicant(s)

JANDACEK ET AL.

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 37-70 and 72-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The response filed **11/16/07** presents remarks and arguments to the office action mailed **5/16/07**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of claims

Claims 1-36 and 71 are pending in this office action.

Claims 37-70 and 72-78 are withdrawn as non-elected specie.

Maintained Claim Rejections - 35 USC § 112

Applicant is argues that 35 U.S.C. § 112 does not require Applicants to redefine in the claim each term when it is sufficiently defined in the specification as in the present case. In the case *In re Fuetterer*, 319 F.2d 259, 138 U.S.P.Q. (BNA) 217 (C.C.P.A. 1963), the U.S. Court of Customs and Appeals decided a case in which the Examiner had rejected the claim that contained "an effective amount ranging from more than incidental impurities". The Examiner stated that it would place an "undue burden...upon the public,

to determine the operable proportions" that would enable the public to practice the invention.

This is not the case here, the rejection, is about ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The undue burden would be a 112-1 enablement rejection which is very different from a 112-2. The two do not overlap.

The rejection is again maintained as in the last office action of record.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 13-14, 16, 19-20, 22, 25-36 and 71 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "from about", "at least about" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack "from" (a lower limit) or "about"(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "from about". Regarding "at least" (a lower limit) or about "(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "at least about".

Claim Rejections - 35 USC § 103

I. Claims 1-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over de Smidt et al. US 6,703,369 B1 in view of Maeder et al. US 6,730,319 B2.

Applicant argues, that the cited reference de Smidt teaches a pharmaceutical composition comprising a glyceride with a melting point of 37 and a lipase inhibitor, but do not teach the stiffening agent.

Also, that Maeder et al. disclose a pharmaceutical composition that is able to transform the active agent after oral ingestion from solid to a liquid, reciting col. 3, lines 42-46.

In response, taking the de Smidt reference for instant the claims recite a pharmaceutical composition comprising at least one fatty acid ester of a polyol and a lipase inhibitor, see col. 1, lines 46-48 having a melting point of 37. Interpreted in Examiners view point is that even though the amended claims now recite ROR, the general teaching of col. 1, line 46-48 to one of ordinary skill in the art would be to substitute the glyceride/glycerol and its sugar alcohol to a fatty acid behenic taught by Maeder, thus behenic has a melting point above 33 and has been used with orlistat to inhibit anal leakage.

As to the amounts the Maeder reference teaches orlistat in varying ratio with the fatty acid, such as 1:1, 2:1 and 4:1. Based on these variation the determination of a dosage having the optimum therapeutic index is well within the level of the ordinary skill in the art, and the artisan would be motivated to determine the optimum amounts to get

the maximum effect of the drug, hence the reference makes obvious the instant invention. The claims are to a pharmaceutical composition, what it does carry no patentability weight. It has been shown that the composition comprises these limitation in the combined references.

Applicant should not that other agents are inclusive in the composition as the term comprising does not exclude other agents.

The above response is related to claims 13-36 as the same arguments were made.

Thus the argument is found unpersuasive.

Claim Rejections - 35 USC § 103

Applicant argues that nowhere does Hug teach, suggest or define any type of a foam compound as considered to be a conventional food grade thickener or emulsifier.

In response, the claims item (b) call for a non-digestable, non-absorbable, open celled polymeric form, which is taught by Hird et al. WO 02/074343. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The argument is found unpersuasive and repeated below.

IV. Claims 31-36 and 71 are rejected under 35 U.S.C. 103(a) as being as unpatentable over de Smidt et al. US 6,703,369 B1 in taken with Maeder et al. US 6,730,319 B2 in view of Hug et al US 6,358,522 taken with Hird et al. WO 02/074343.

With regards to claim 31 de Smidt et al. teach a pharmaceutical composition comprising (i) a glyceride ester (thus R-OR' which is per definition a stiffening agent) (see col. 1 lines 50+), R is C₁₂₋₂₀) (see col. 3, line 60), with a melting point of 37°C and a lipase inhibitor (see col. 1 lines 46+) as in claim 35 and 71, wherein the stiffening agent is at least 5% (see col. 4, lines 38-65) as in claim 33.

As to claim 32, the stiffening agent is a fatty acid (see abstract), wherein the lipase inhibitor is a tetrahydrolipstatin (known as orlistat) (see col. 1 lines 10+) as in claims 35 and 36.

Maeder et al. also teach having a pharmaceutical composition containing a lipase inhibitor, a fatty acid having a melting point equal or greater than 37°C, (see col. 1 lines 7-21), wherein the fatty acid is selected from behenic acid (see col. 5, lines 43+) as in claim 31(ii).

Hug et al. teach a pharmaceutical compositions containing an inhibitor of gastrointestinal lipases, one (or more) additive(s) of the group consisting of substantially non-digestible food grade thickeners and emulsifiers, and excipients (see abstract) wherein the compositions are useful for inhibiting anal oil leakage (see col. 1, lines 56-57).

Hird et al. teach composition comprising a non-digestible, non-absorbable, open-celled polymeric foam (see abstract and page 5 second para. from the bottom) wherein the compositions are useful for inhibiting lipids or lipophilic materials present in the GI for anal leakage see pages 8 (last para. bridging page 9).

One of ordinary skill would have combined the teachings of de Smidt et al. with that of Maeder et al. choose the fatty acid calcium stearate and expect a successful result in doing so because both cited references teaches using fatty acid and substituting the specific fatty acid of Maeder et al. would have been obvious.

Further on of skill would be motivated to combine the teachings of de Smidt et al. taken with Maeder et al in view of Hug et al. for the absorption of oil as taught by Hug et al. in the treatment of anal oil leakage. Also, one of ordinary skill in the art would be motivated to combine the cited art add a non-digestive, non-absorbable, open celled polymeric foam because this composition can be used to treat anal leakage as taught by Hug et al. (see col. 1, lines 58-66) and as taught by Hird et al. these open celled forms are non-digestable (see page 9, last para) wherein the open celled foams inhibit digestion by the gastric fluid)

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
2/1/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Application Number**Application/Control No.**

10/699,351

**Applicant(s)/Patent under
Reexamination**

JANDACEK ET AL.

Examiner

Shirley V. Gembeh

Art Unit

1614